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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,693	06/27/2000	Markus Pompejus	BGI-130CP	4996

959 7590 06/16/2004
LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/604,693

Applicant(s)

POMPEJUS ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-16 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 6,39-41 is/are allowed.
- 6) ☒ Claim(s) 5,7,15,16 and 42 is/are rejected.
- 7) ☒ Claim(s) 1,7 and 10-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicants cancellation of claims 2, 3, 8, 9 and 17-38, amendment of claims 1, 4-7, 13, 15, 16 and the addition of claims 39-42, in the Paper 3/24/2004, is acknowledged. Claims 1, 4-7, 10-16 and 39-42 are still at issue and are present for examination.

Applicants' arguments filed on 3/24/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

As previously stated, no information disclosure statement is currently associated with this application.

Applicants acknowledgement of the above lack of submission and their intent to submit such an information disclosure statement in due course is acknowledged.

Specification

The disclosure is objected to because of the following informalities:

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On page 28, lines 11-14, of the specification applicants state "As used herein, the term 'hybridizes under stringent conditions' is intended to describe conditions for hybridization and washing under which nucleotide sequences at least 60% homologous to each other typically remain hybridized to each other..." Such a statement that nucleotide sequences which are 60% homologous would hybridize under stringent conditions is considered to be repugnant to what is known in the art.

Applicants have not responded to the above objection to the specification which was stated in the previous office action.

Appropriate correction is required.

Claim Objections

Claims 1, 7 and 10-16 are objected to because of the following informalities:

Claim 16 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claim 16 is dependent on claims 15 and 42 and claim 15 is dependent on claims 12 or 42.. See MPEP § 608.01(n). Accordingly, the claim 16 not been further treated on the merits.

Claims 1 (claims 10-16 dependent from) and 7 are objected to for the recitation "or a complement thereof." It is suggested that this be amended to "or a full complement thereof" in order to maintain consistency with newly added claim 39.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16 and 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "said fine chemical" in claim 15 or 42. There is insufficient antecedent basis for this limitation in claim 42.

Claim 42 (claim 15 dependent on) is objected to for the recitation "said cell". It is suggested that this be amended to said host cell". As discussed in the previous office action for claim 13 and to maintain consistency.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 7 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to claims 5-9 and 36-38. In response to this rejection, applicants have canceled claims 8, 9 and 36-

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38, and amended claims 5-7 and traverse the rejection as it applies to the newly amended and added claims.

Applicants traverse the rejection on the basis that there is sufficient written description in applicants specification regarding nucleic acid molecules comprising SEQ ID NO: 1 and nucleic acid molecules with a significant degree of homology to SEQ ID NO: 1 and SEQ ID NO: 2, which encode polypeptides which are capable of functioning as extracellular nucleases, to inform a skilled artisan that Applicants were in possession of the claimed invention at the time the application was filed as required by section 112, first paragraph. Applicants further submit that in order to meet the written description requirement of 112 first paragraph, it is not necessary that a patent specification describe each and every specific member of a genus recited in a claim.

Applicants specifically traverse the rejection of claim 5 on the basis that any and/or all polynucleotides but rather is directed only to those which encode functional extracellular nucleases that are encoded by a nucleic acid with a high degree of identity to SEQ ID NO: 1 and which hybridize under the recited conditions. Applicants point out that the recited hybridization conditions determine a specific subgenus of molecules in accordance with the invention.

Applicants further reference Example 14 of the Revised Interim Written Description Guidelines Training Materials which provides a claim that is directed to variants of a polypeptide having SEQ ID NO: 3 that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A-B. Applicants argument as it applies to claims 6

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and 41, is found persuasive, as applicants will notice that claims 6 and 41 have not been included in the current rejection.

With respect to claim 5, claim 5 remains rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to polynucleotides encoding naturally occurring allelic variants of a disclosed polynucleotide that encodes a extracellular nuclease.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

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In the instant specification, a single gene encoding SEQ ID NO: 2 is fully described in the form of SEQ ID NO:1, wherein SEQ ID NO: 2 has extracellular nuclease activity. This description also adequately describes a genus, within the sequence identity limitations of the instant claims, of polynucleotides encoding proteins having this particular function. Those sequences that are "naturally occurring" are a subset of this genus. The specification does not adequately describe this subset according to its structure so that one of skill in the art would be able to predict naturally occurring allelic sequences, particularly in view of the larger genus that includes both naturally and "manufactured" sequences. Therefore, the instant claim 5 is not adequately described.

With respect to claim 7, which is directed to an isolated nucleic acid molecule which encodes a polypeptide fragment comprising at least 25 contiguous amino acid residues of the amino acid sequence of SEQ ID NO: 2, applicants submit that they have described various fragments of the polynucleotides of the invention.

Presumably in support of applicants position with respect to claim 7, applicants refer to Example 15 of the *Interim Guidelines for Examination of Patent Applications Under the 35 USC 112 first paragraph written description* Requirement and submit that similarly to Example 15, the instant specification describes the nucleotide sequence of the nucleic acid molecules of the invention (SEQ ID NO: 1) which define and limit the structure of any nucleotide fragments such that one of skill in the art would be able to immediately envisage members of the embraced genus.

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Applicants argument has been considered in full but is found non-persuasive. As an initial matter, applicants attention is directed to applicants current amendment of claim 7 which is in fact drawn to an "isolated nucleic acid molecule comprising a fragment of at least 25 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 1, or a complement thereof".

While applicants specification with its teachings including the sequence of SEQ ID NO: 1 describes many fragments of SEQ ID NO: 1 which are encompassed in the claimed genus, applicants have not sufficiently described the genus claimed which is drawn to those nucleic acid molecule comprising a fragment of at least 25 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 1, or a complement thereof. The claimed genus is far larger then fragments of SEQ ID NO: 1 (a 965 nucleotide molecule), but rather includes many additional polynucleotide variants, potentially both naturally occurring as well as man-made encompassed with in this genus and applicants have only described those members of the genus that are fragments of SEQ ID NO: 1.

Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. It is noted that applicants claims read on a genus of nucleic acid molecules and host cells comprising said nucleic acid molecules, wherein the nucleic acid molecules have no functional limitations, relatively minor structural limitations and thus absolutely no structure to function/activity relationship.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

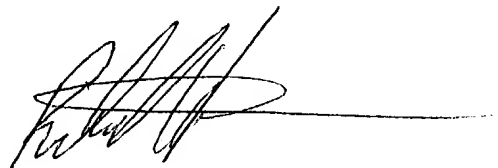
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax

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phone number for the organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', followed by a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
6/1/2004